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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,722	09/19/2008	Patrick Lewis Blott	SMNPH.008APC	3283

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EXAMINER

SU, SUSAN SHAN

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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04/08/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,722	BLOTT ET AL.	
	Examiner	Art Unit	
	SUSAN SU	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-44 is/are pending in the application.
- 4a) Of the above claim(s) 38-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/3/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 38-44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The new claims 38-44 are directed at an apparatus comprising a backing layer, a *manifold comprising radial channels*, a fluid supply tube, a fluid offtake tube, a regulator, a pressure monitor, and at least one pump.

Under PCT Rule 13.1, the expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions considered as a whole, makes over the prior art. The above two groups do not relate to the same single general inventive concept as the *original* claims under PCT Rule 13.1. Although they share special technical features (i.e. backing layer, fluid supply tube, fluid offtake tube, pump, and a regulator), these special technical features do not define a contribution over the prior art because they are either obvious or anticipated by US 6,824,533 (as detailed in the Non-Final Office Action of 5 October 2010). Accordingly, the special technical features linking the inventions do not provide a contribution over prior art, and subsequently no single general inventive concept exists. Therefore the restriction is appropriate.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-44 are withdrawn from consideration

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as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of Claims

Claims 15-44 are pending of which Claims 15 & 20 are amended and Claims 25-44 are new. Claims 38-44 are withdrawn from consideration as being directed to non-elected invention by original presentation and Claims 1-14 have been canceled by this amendment, thus Claims 15-37 are examined on the merits. No new matter is added.

Response to Arguments

2. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendments to the claims.

Specification

Acknowledgement is made of amendments filed 3 February 2011 to the Specification to correct minor informalities.

Drawings

3. Figures 11a, 13b, 15, 16b, 18b, and 22 are objected to because Fig. 11a lacks reproductive quality (particularly the numbers) as required by 37 CFR 1.84(l) and there lacks any labeling for the remaining figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be

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labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 15, 16, 18-24, 26-28, 31-33, & 37 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Lockwood et al. (US 2005/0004534, "Lockwood").

Re Claim 15, Lockwood teaches a method of treating a wound to promote wound healing, the method comprising:

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providing a fluid flow path, the fluid flow path comprising a conformable wound dressing (14), having a backing layer (film 13 or 450) forming a fluid-tight seal over a wound, the backing layer comprising a wound facing face, a fluid supply tube (e.g. 72 & 76 or through vent passageway since air is also a fluid; see also Fig. 36 of 2002/0082567, hereinafter '567, which is incorporated by reference), and a fluid offtake tube (e.g. 70 & 74); moving fluid from a fluid reservoir (18 or atmosphere) through the fluid flow path;

regulating the amount of fluid that flows through the fluid supply tube (implied in [0155] or through vent assembly 80/180); and

regulating the amount of fluid that flows through the fluid offtake tube (implied in [0155]);

wherein fluid is moved through the fluid flow path to provided simultaneous aspiration and irrigation to the wound ([0166] or "vented vacuum" or "vented irrigation" [0094] or Fig. 36 of '567);

wherein fluid moving through the fluid flow path is regulated to hold negative pressure on the wound at a steady level while providing simultaneous aspiration and irrigation to the wound ([0155]).

Re Claim 16, Lockwood also teaches that both regulating the amount of fluid that flows through the fluid supply tube and regulating the amount of fluid that flows through the fluid offtake tube comprise regulating the amount of fluid with a pump (e.g. through

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vacuum pump 110 or syringe 24 with plunger 70, in 2002/0198503, hereinafter Risk '503, which is incorporated into Lockwood by reference).

Re Claims 18 & 19, Lockwood also teaches that at least one of regulating the amount of fluid that flows through the fluid supply tube and regulating the amount of fluid that flows through the fluid offtake tube comprises regulating the amount of fluid with a regulator, wherein the regulator is a valve (valve 130 controlled by controller 50, in Risk '503).

Re Claim 20, Lockwood teaches an apparatus for aspirating, irrigating and/or cleansing wounds, comprising:

- a backing layer (e.g. film 13) capable of forming a fluid-tight seal over a wound;
- a fluid supply tube (e.g. 72 & 76, or vent passageway since air is also a fluid) arranged to provide fluid from a fluid reservoir (e.g. atmosphere, or syringe 24 of Risk '503) to the wound;
- a fluid offtake tube (e.g. 70 & 74) arranged to withdraw fluid from the wound;
- a pump (110 of Risk '503) in communication with at least one of the fluid supply tube and the fluid offtake tube and configured to move fluid through at least one of the fluid supply tube and the fluid offtake tube;
- a regulator (e.g. valve 427 of Lockwood or controller 50 that controls pump 110 and valve 130 of Risk '503) in communication with at least one of the fluid supply tube and the fluid offtake tube and configured to at least

regulate the rate of fluid flowing through at least one of the fluid supply tube and the fluid offtake tube ([0084] of Risk '503); and

a pressure monitor (124 of Risk '503) configured to monitor negative pressure under the backing layer (since Risk '503 teaches in [0087] that valve 130 is opened/closed to change the pressure applied to the bandage 14 based on the reading from pressure sensor 124, implying that the pressure reading from sensor 124 is indicative of the level applied to the wound);

wherein the apparatus is configured to provide simultaneous aspiration and irrigation to the wound such that fluid may be supplied to the wound from the fluid reservoir via the fluid supply tube while fluid is aspirated through the fluid offtake tube ([0166] or Fig. 36 of '567); and

wherein, based on the monitored negative pressure, the regulator is configured to hold negative pressure on the wound at a steady level ([0087] of Risk '503) while simultaneous aspiration and irrigation is provided to the wound ([0166] Lockwood).

Re Claims 21 & 24, Lockwood also teaches by incorporation that the regulator is a valve (130 of Risk '503) or a pump (e.g. through vacuum pump 110 or syringe 24 with plunger 70 of Risk '503).

Re Claims 22 & 23, Lockwood also teaches by incorporation that the pump (syringe 24 with plunger 70, Risk '503) is in communication with the fluid supply tube and is configured to move fluid through the fluid supply tube, and the regulator (valve 130 controlled by controller 50, Risk '503) a second pump (pump 110, also controlled by

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controller 50, Risk '503) is in communication with the fluid offtake tube and is configured to regulate the rate of fluid flowing through the fluid offtake tube and to move fluid through the fluid offtake tube.

Re Claim 26, Lockwood also teaches by incorporation that at least one of the pump and the second pump (110) comprises a fixed-speed pump ([0059] of Risk '503, it is also disclosed that valve 130 and vacuum regulator 134 limit and vary the output of pump 100, further supporting that the pump is fixed-speed).

Re Claim 27, Lockwood also teaches by incorporation that

the pump (syringe 24 with plunger 70, Risk '503) is in communication with the fluid supply tube and is configured to move fluid through the fluid supply tube;

the regulator comprises a second pump (110, Risk '503) in communication with the fluid offtake tube and configured to move fluid through the fluid offtake tube; and

the regulator (which may also include valve 130, Risk '503) is configured to regulate the rate of fluid flowing through the fluid offtake tube ([0057]).

Re Claim 28, Lockwood also teaches that the regulator comprises a valve (e.g. 472) configured to vent the wound from atmosphere.

Re Claim 31, Lockwood also teaches a non-return valve (e.g. vent-valve assembly 80, 180) in communication with the fluid supply tube and configured to avoid overpressure on the wound.

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Re Claim 32, Lockwood also teaches that regulating fluid moving through the fluid flow path to hold negative pressure on the wound at a steady level while providing simultaneous aspiration and irrigation to the wound comprises monitoring (through sensor 124 of Risk '503) negative pressure under the backing layer.

Re Claim 33, Lockwood also teaches by incorporation adjusting negative pressure in response to monitoring negative pressure under the backing layer ([0057] and [0087] of Risk '503).

Re Claim 37, Lockwood also teaches by incorporation that regulating the amount of fluid that flows through the fluid supply tube is independent of regulating the amount of fluid that flow through the fluid offtake tube (e.g. irrigation flow is driven by drive motor 72 whereas vacuuming is regulated by valve 132).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood in view of Harris (US 5,030,202). Lockwood substantially teaches the claims but does not explicitly teach that at least one of regulating the amount of fluid that flows through the fluid supply tube or fluid offtake tube comprises regulating the amount of fluid with a variable speed pump or that the regulator is a variable speed pump. Harris teaches a medical system that provides aspiration and irrigation to tissue, wherein the system comprises a variable speed pump to control the aspiration rate (Claim 12). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lockwood with Harris for the purpose of having an alternative way to control the rate at which fluid is delivered to the wound.

10. Claims 29, 30, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood in view of Zamierowski (US 6,071,267).

Re Claims 29 & 34, Lockwood does not teach explicitly that the pressure monitor (124 of Risk '503) is connected to *a monitor offtake tube* but rather that it is connected

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to the fluid flow pathway. Zamierowski teaches a vent tube (Fig. 3 where vent 35 is connected) in addition to fluid flow path for irrigation/aspiration. Since it is well known in the art that pressure sensor may be placed in a pathway to monitor the pressure, it is within the knowledge of one skilled in the art to rearrange the pressure monitor of Lockwood/Risk '503 to the vent tube of Zamierowski for the purpose of avoiding blocking the fluid flow path.

Re Claims 30 & 35, Lockwood teaches a regulator (e.g. vent assembly 80/180) on a vent tube (e.g. vent passageways 226 or 284) but it is not configured to be operable during simultaneous irrigation and aspiration. However, duplication of the regulator and rearranging such a regulator to the vent tube of Zamierowski (portion of which can read on the bleed tube and the other portion directly connected to the pressure sensor can read on the monitor offtake tube) are within the knowledge of one skilled in the art. One would also be motivated to do so for the purpose of having fine adjustment controls over the pressure experienced by the wound. After the modification, the regulator on the vent tube would read on the bleed regulator and also configured to regulate the rate of fluid that flows through the fluid offtake tube (i.e. if the regulator is open then the fluid would be able to exit through the bleed/vent tube thus decreasing flow through the fluid offtake tube).

11. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood. Lockwood does not teach in the same embodiment that simultaneous aspiration and irrigation takes place with operating a bleed regulator (interpreted to mean a device that allows inflow or outflow from the surrounding environment into the

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fluid flow path). However, Lockwood teaches operating bleed regulator connected to the fluid flow path during either irrigation or aspiration (e.g. vent assembly 180 that allows air inflow/outflow with the atmosphere, [0094]-[0103]) to regulate fluid that flows through the fluid offtake tube (i.e. during aspiration there would be fluid flowing through the fluid offtake tube). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lockwood's simultaneous aspiration/irrigation method with the added safety of a bleed regulator to help prevent against pressures that are too high/low under the dressing.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
29 March 2011

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
5 April 2011